skeletal dynamics

K092720

JUN 29 2010

510(k) Summary of Safety and Effectiveness
Wrist Arthrodesis Nail System System

June 18, 2010

Submitter:
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FDA Establishment Registration Number: Pending

Trade Name, Common Name, Classification:
Device Trade Name: Wrist Arthrodesis Nail System
IMPlate Wrist Arthrodesis Nails

Device Common or Usual Names: Intramedullary fixation rod

Product Code: HSB

Classification: Class II, 21 CFR 888.3020

Predicate Device:
Synthes – LCP Wrist Fusion – K042355

Description of the Device:
The Wrist Arthrodesis Nail System is designed as an intramedullary nailing platform to address wrist arthrodesis procedures utilizing a minimally invasive dorsal approach into the third metacarpal and distal radius by trained physicians. The IMPLATE Wrist Arthrodesis Nails are secured within the intramedullary canals by means of bone screws, and then assembled into a completed construct using a Connector.

The IMPLATE Wrist Arthrodesis Nail System is comprised of a titanium (Ti 6AL-4V) Distal Radius Intramedullary Nail, various lengths of titanium (Ti 6AL-4V) Metacarpal Intramedullary Nails, multiple titanium (Ti 6AL-4V) nail Connectors in various lengths and angles, and Unicortical Screws of various lengths, Pins and System specific instrumentation

Intended Use:
The Wrist Arthrodesis Nail System is intended for wrist arthrodesis. Specific indications include post-traumatic arthritis of the joints of the wrist, rheumatoid wrist deformities requiring restoration, complex carpal instability, post-septic arthritis of the wrist, severe unremitting wrist pain related to motion, brachial plexus nerve palsies, tumor resection, and spastic deformities.

Technological Characteristics:
The Wrist Arthrodesis Nail System has the following similarities to the LCP Wrist Fusion manufactured and distributed by Synthes pursuant to K042355:

- The same indications for use and intended use
- The same materials
- The same load strength
- Accommodate different size anatomies.

Biocompatibility:
The materials selected for the Wrist Arthrodesis Nail System have a long history of safe use in the orthopedic industry. The materials are medical grade titanium alloy and cobalt chrome.

Comparison of Technological Modifications:
In contrast to the predicate device, the Wrist Arthrodesis Nail System was designed to be placed within the medullary canal. Placement within the medullary canal reduces the possibility of soft tissue irritation and subcutaneous prominence. Intramedullary placement also minimizes the size of the surgical incision.

Summary of Non-Clinical Testing:
The following tests were performed to demonstrate that the Wrist Arthrodesis Nail System is safe and effective:

- Static four point bending test in accordance with ASTM F82 was performed to determine the bending strength of the subject device and compare the yield point and bending stiffness to that of the predicate. All subject devices tested passed the acceptance criteria without failure.
- A dynamic four point bending test in accordance with ASTM F1264 was performed to determine the maximum run out value at 1,000,000 cycles. The testing confirmed the endurance value of 1,000,000 cycles without evidence of failure.
- A torque test was performed to challenge the strength of the connector. All subject devices tested passed the acceptance criteria without evidence of failure.
- A pull test was performed to challenge the interconnection of the connector to the metacarpal and radius nails. All subject devices passed the acceptance criteria without evidence of failure.
- A cadaver lab was performed to confirm the repeatability of the surgical procedure. The lab documented that the procedure is feasible and repeatable.

Conclusion:
We believe the subject device is substantially equivalent to the predicate device and conclude that the subject device is as safe and effective as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Skeletal Dynamics, LLC
% Ms. Ana M. Escagedo
Vice President Quality & Regulatory Affairs
8905 Southwest 87 Avenue, Suite 102
Miami, Florida 33176

JUN 29 2010

Re: K092720
Trade/Device Name: Wrist Arthrodesis Nail System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: II
Product Code: HSB
Dated: June 22, 2010
Received: June 23, 2010

Dear Ms. Escagedo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K092720

Device Name: Wrist Arthrodesis Nail System

Indications For Use:

The Wrist Arthrodesis Nail System is intended for wrist arthrodesis. Specific indications include post-traumatic arthritis of the joints of the wrist, rheumatoid wrist deformities requiring restoration, complex carpal instability, post-septic arthritis of the wrist, severe unremitting wrist pain related to motion, brachial plexus nerve palsies, tumor resection, and spastic deformities.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K092720